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Michigan Community Blood Centers Response to Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods Docket No. 2005D-0330

December 28, 2005
Dear Docket Offices,

Michigan Community Blood Centers (MCBC) is an independent community based blood center who performs whole blood and apheresis collections for the local community. We appreciate the opportunity to comment on this Guidance. Our comments are as follows:

Comment 1: Restriction of the number of products collected from individual donors to no more than 24 products per year with doubles and triples counting as multiples.

It appears that a perceived Donor Safety issue is driving this change, however no data is provided to justify the change. MCBC can provide years of data to show that platelet counts remain stable throughout a long donation history.

Comment 2: Interpretation of Medical Coverage (e.g. physician) availability with 15 minutes in case emergency need.

The current state of equipment for platelet pheresis encompasses built in donor safeguards as noted in the lower incidence of donor reactions than exist with whole blood donations. In the event that an emergency occurred, we believe that it is safer to rely on trained staff, a validated emergency response plan, and trained emergency personnel rather than reliance on physicians who may not have an emergency response background.

Comment 3: Extension of donor deferral for ingestion of drugs that affect platelet activity.

We do not believe that data supports the extension of this list, and have seen no deleterious effects in practice.

Comment 4: Use of SCAN statistics for validations and Quality Control. Use of SCAN statistics as outlined in the draft guidance involves large numbers of products which would be difficult to manage for small centers. The implementation of SCAN statistics without readily available computer software and trained staff would be extremely difficult.

These proposed guidance requirements would decrease the availability of pheresis donors and consequently pheresis products.

We appreciate the opportunity to response to this draft Guidance.

Sincerely, 2005D-0330

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Lee Ann Weitekamp
Medical Director